Remarks/Arguments

Claims 15-39 are currently pending in this application. Claims 15-20, 23, 30, and 31 have been withdrawn. Claims 24-25 have been canceled. New claims 40-52 have been added. Claims 21-22, 28-29, 32-33, and 35-38 have been amended.

Claims 21-22, 24-29, and 32-39 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application Nos. 11/153,728; 11/119,273; and 11/219,273. The Examiner has rejected claim 32 under 35 U.S.C. §112 second paragraph as being indefinite. The Examiner has rejected claims 21-22, 24-29, 32-39 under 35 U.S.C. §102(a,e) as being anticipated or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Webb (U.S. Publication No. 2003/0114389).

Double Patenting

The Examiner has provisionally rejected claims 21-22, 24-29 and 32-39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application Nos. 11/153,728; 11/119,273; and 11/219,273. Applicant maintains its request that the Office hold all provisional double patenting rejections in abeyance pending claim allowance.

35 U.S.C. §112

The Examiner has rejected claim 32 under 35 U.S.C. §112 second paragraph as being indefinite. Applicant has amended claim 32 to properly depend from claim 28. In view of this amendment, Applicant submits that claim 32 is now in condition for allowance.

35 U.S.C. §102/103

The Examiner has rejected claims 21-22, 24-29, 32-39 under 35 U.S.C. §102(a,e) as being anticipated or, in the alternative, under 35 U.S.C. §103(a) as being obvious over Webb (U.S. Publication No. 2003/0114389). The Examiner asserts that Webb teaches a composition comprised of 100mg of aliskiren in the hemi-fumerate salt form, a filler, a disintegrant, a lubricant, a glidant, a binder, and a film coating. Applicant notes that the "filler" identified by the Examiner is never used or identified as being useful in an aliskiren formulation. Rather, Example 2 of Webb refers to the use of microcrystalline cellulose in a nateglinide formulation.

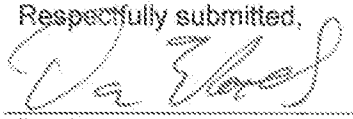
The instant invention, as amended, is directed to a solid oral dosage form of aliskiren, or a pharmaceutically acceptable salt thereof, in the form of a tablet, comprising the active ingredient in an amount higher than 46% by weight and with a) an inner phase which comprises the active ingredient, a filler, a binder, and a disintegrant, and b) an outer phase which comprises a disintegrant, a filler, a glidant, and a lubricant. Applicant respectfully submits that Webb fails to disclose, teach or suggest such a solid oral dosage form of aliskiren. The invention of Webb relates to a combination of aliskiren and at least one antidiabetic agent.

Specifically, Example 1 of Webb describes an aliskiren tablet formulation having an inner and outer phase, but with all the disintegrant excipient placed in the outer phase, so the inner phase has no disintegrant. Moreover, the instantly claimed formulation does not contain the glidant except in the outer phase.

As mentioned in paragraphs [0006]-[0009] of the instant application, aliskiren is a difficult drug to formulate and, up to the date of the invention, it was not possible to make oral formulations in the form of tablets in a reliable and robust way and with the appropriate quality standards. In addition, due to the low oral bioavailability of aliskiren, high amounts of this active ingredient are required in the oral dosage forms which makes formulation of aliskiren in the form of tablets even more difficult. Bioavailability is the amount of an administered drug that becomes available for activity in the target tissue, and alterations in the bioavailability of a drug may reduce its efficacy or result in a toxic effect. For instance, if the tablet does not break down properly it would result in low bioavailability and reduced efficacy in the patient. In this regard, disintegration refers to the physical process by which a tablet breaks down completely into fine particles.

The inventors of the instant invention found that it was important to have the disintegrant excipient in both the inner and outer phase of the tablet in order to have a suitable disintegration time. The disintegration time is the length of time required for causing disintegration of a tablet which is important for evaluating a tablet because disintegration time may influence the bioavailability and efficacy of a drug. Thus, long disintegration times of a tablet may reduce bioavailability of the drug. Accordingly, taking into account that aliskiren is poorly absorbed because of its low bioavailability (its oral bioavailability is only about 2.5%), the disintegration time of the tablet in which this drug is formulated can be critical for its efficacy. Thus the use of a disintegrant in both layers of the instantly claimed tablet allows for a faster dissolution time and greater bioavailability. As the formulation of Webb does not have disintegrant in the inner layer it would be unable to achieve the dissolution of the instantly claimed invention. Accordingly, as Webb fails to disclose, teach or suggest inclusion of a disintegrant in the inner layer of the tablet, Applicant respectfully submits that the instantly claimed invention is both novel and inventive over Webb.

Respectfully submitted,



Daniel Woods
Attorney for Applicant
Reg. No. 59,864

Novartis Pharmaceuticals Corporation
One Health Plaza, Bldg. 101
East Hanover, NJ 07936
+1 862 7789587

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